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Serial No. 10/645,089

PATENT

REMARKS

In the Office action of February 16, 2006, Paper No. 02072006, claims 1-34 are pending of which claims 1-34 were rejected.

In particular, claim 16 was objected to under 35 USC 112.

Claims 1, 4-5, 8-10, 12, 16-17, 19, 22-23, 26 and 30-34 were rejected under 35 USC 102(b) as anticipated by Rodriguez (US Pat 5421349). Claims 2-3 and 27 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Lafontaine (US Patent 5662621). Claims 7 and 11 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Erickson (US Patent 5664580). Claims 13 and 20 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Worley (US Pub 20030208141). Claim 14 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez and Lafontaine in view of Worley. Claim 15 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez and Lafontaine in view of Connors (US Pub 20040039304). Claims 21, 24-25 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Connors. Claims 6, 18, 28-29 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Connors and further in view of Cornelius (US Pat 5924998).

With reference to the objection to the title we thank the Examiner for his suggestion of a more appropriate title and request that the title be amended to read:

VARIABLE STIFFNESS ATRAUMATIC GUIDE WIRE

With reference to the objection to the priority claim raised in paragraph 2 of the Office Action we submit that the Examiner has mistakenly compared different dimensions in the priority document and the present specification. The dimension of 5 to 15 centimeters in the priority document 60405161 for the preformed curve at the distal end of the guide wire is correctly compared with

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the dimension of 5 to 15 centimeters being the distal curve 6 as shown in Figure 7 and as discussed at page 11 lines 18 and 19. The dimension of 5 mm to 20 mm refers to the radius of the tip curve 16 as shown in Figure 7 and as discussed at page 11 lines 14 to 16. The corresponding component in the priority document is the flexible portion formed into a pigtail or spiral but for which no specific dimension is given in the priority document. We trust that this clarifies the relationship between the specifications for the examiner and we submit that the claims 15 and 21 are entitled to the priority claim.

In the amendments to the claims, claims 2, 5 -6, 10, 13, 15 -27, and 29 to 34 are cancelled. Claims 1, 3, 4, 9, 14 and 28 are amended and new claim 35 is added. We submit that in making these amendments no new subject matter has been added. The added material in claim 1 comes from page 12 lines 4 to 5, original claim 2, part of original claim 3 and original claim 21. The amendment to claim 3 is to delete that material which has been included into claim 1. The added material in claim 4 comes from original claim 5. The added material in claim 9 comes from original claim 10. The amendment to claim 14 is to remove that part added into claim 1, to correct the dependency and to clarify the terminology. The amendment to claim 28 is to correct the dependency.

The new claim 35 is we submit a combination of parts of original claims 4, 5, 9, 10 and 18.

We submit that the cancellation of claim 16 has rendered moot the objection under 35 USC 112.

Claim 1 as amended, now defines a guide wire which has three distinct zones each of which has a specific characteristic and in particular the proximal and distal zones have been more clearly defined. The proximal zone is specifically formed as described in claim 1 to be able to be deployed into the nose cone of an endovascular deployment device without spearing into the sides

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of a lumen of a guide wire catheter (see page 10 line 29 to page 11 line 9) and particularly in the nose cone dilator region of an endovascular deployment device which is formed from relatively soft elastomeric materials. The central zone is of high stiffness and constant diameter to assist with deployment of the endovascular deployment device over it by being stiff enough to straighten the vasculature (page 10 lines 3 to 6). The distal zone has a pre-formed curve to enable it to take up the shape of the thoracic arch of a patient (page 10 lines 10 to 13) and to anchor the guide wire into the aorta during advancement of the endovascular deployment device (page 9 lines 18 to 22). The tip curve is highly flexible to avoid damage to the vasculature and particularly the aortic valve of the heart (page 9 lines 22 to 27). We submit that the combination of all of these features is not present in any of the cited art and particularly Rodriguez (US Pat 5421349).

Rodriguez (US Pat 5421349) discloses a guide wire which has a central portion which while being described as being stiffer than the distal tip is clearly illustrated as being relatively flexible. The proximal tip of the Rodriguez device is very short, "no more than two inches" (column 2 lines 27 to 28) and is intended to be pushed by a gloved hand. It is clearly not intended to be a guide wire on which a deployment device can be advanced in the vasculature of a patient. This can be understood further because the central portion appears to have a region of protrusion (item 19 in Figure 1) and the description at column 3 line 67 to column 4 line 1 describes the use of the device to push a coil through the vasculature of a patient. Rodriguez does not disclose or teach a guide wire which has an elongate central zone of high stiffness and substantially constant diameter along its length to straighten out the vasculature, a proximal zone of transition from high stiffness to semi-stiffness and having a length of from 3 cm to 20 cm to be able to be fed back through the guide wire catheter of an

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endovascular delivery device and a distal zone having three zones of transition from high stiffness to being relatively flexible and in which the distal zone has a pre-formed curve with a radius of curvature of from 5 cm to 15 cm to hook into the thoracic arch and also a tip curve with a radius of curvature of from 5 to 20 mm to prevent damage to the vasculature and heart valves.

As discussed above all of the features in claim 1 of the present application are specified for a purpose and the device of Rodriguez does not have these features and could not be used for that purpose. For these reasons we submit that claim 1 is not anticipated and is novel over Rodriguez.

Claims 4, 8, 9 and 12 are rejected as being anticipated over Rodriguez. We submit that these claims depends from a novel and not anticipated claim and that these claims are also novel and not anticipated.

Claim 3 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Lafontaine (US Patent 5662621). Lafontaine discloses a guide catheter and not a guide wire. The guide catheter has a lumen therethrough through which can be deployed a guide wire or other therapeutic device. The guide catheter is formed from a shape memory material and has three heating zones. It is preformed into a selected shape and then straightened for use by heating. When cooled within the body of a patient it takes up its preformed shape so that a device extended through the catheter and can be directed as desired. There is no teaching or suggestion of the use a preformed curve at the distal end of a guide wire. There is also no teaching or suggestion in Lafontaine that each of the heating zones has a different flexibility than other of the zones. With respect to the Examiners comments we submit that Lafontaine does not disclose a stainless mandrel of high stiffness but the feature 24 in Figure 1, to which the Examiner refers, is in fact formed from alternating metallic sections and elastomeric joints to provide flexibility to guide the guide catheter

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through the tortuous pathways of a patient's vascular system (column 5 lines 12 to 17). There is certainly not a central zone of high stiffness as is claimed in claim 1 and the central zone is not a stainless steel mandrel as claimed on claim 3. We submit that the combination of Rodriguez and Lafontaine is not properly made because they relate to different types of devices for different purposes and further that the combination of Rodriguez and Lafontaine does not teach or suggest the invention as claimed in claim 3.

Claims 7 and 11 were rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Erickson (US Patent 5664580). Erickson discloses a guide wire in which the distal coil is partially radiopaque and that the coil can be laser welded to the wire. We submit, however, that the combination of Rodriguez and Erickson does not teach the invention as claimed in claims 7 and 11 because neither disclosure separately or in combination teaches or suggests the construction claimed.

Claim 14 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez and Lafontaine in view of Worley. In a similar manner to Lafontaine Worley does not disclose a guide wire but a guide catheter or guiding introducer for introducing specialized medical devices into the coronary sinus (paragraph [0002]). The device of Worley does have a distal curve. The distal curve of Worley does not, however, have varying flexibilities along its length as is claimed in the present application. We submit that none of Rodriguez, Lafontaine or Whorley either individually or in any combination teach or suggest the combination of features which are claimed in claim 14. None of these references, for instance, disclose, teach or suggest a central zone of high stiffness and a distal curve zone of varying stiffness. We submit that the combination of Rodriguez, Lafontaine and Whorley does not teach or suggest the invention as claimed in claim 14.

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Claim 28 was rejected under 35 USC 103(a) as being unpatentable over Rodriguez in view of Connors and further in view of Cornelius (US Pat 5924998). Connors. Cornelius discloses zones of varying lubricity along the length of a guide wire and in particular a lubricious distal portion and a less lubricious intermediate portion and a radiopaque distal tip. Connors similarly discloses zones of varying lubricity along the length of a guide wire and in particular a lubricious distal portion and a less lubricious easier to grip proximal portion. We submit, however, that the combination of Rodriguez, Connors and Cornelius does not teach the invention as claimed in claim 28 because none separately or in combination teaches or suggests the construction claimed.

New claim 35 is not, we submit, taught or suggested by any of the citations raised against this application either separately or in any combination.

The objections of anticipation of claims 5, 10, 13, 16-17, 19, 22-23, 26 and 30-34 are, we submit, rendered moot by the cancellation of these claims.

The objections of unpatentability of claims 2, 6, 13, 18, 21, 24, 25, 27 and 29 are, we submit, rendered moot by the cancellation of these claims.

The reexamination and reconsideration of this application is respectfully requested, and it is further requested that the application be passed to issue.

Although the foregoing discussion is believed to be dispositive of the issues in this case, applicants' attorney requests a telephone interview with the Examiner to further discuss any unresolved issues remaining after the Examiner's consideration of this amendment

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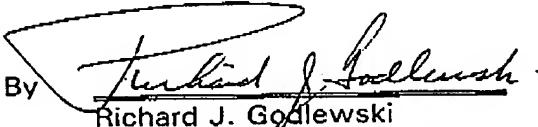
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Respectfully submitted,
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